UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,233	05/07/2007	Malin Ernebrant	02508.0110	9327

22852 7590 09/22/2010

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
FISHER, ABIGAIL L	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
09/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,233	ERNEBRANT ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 27-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/2/07 and 7/3/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-25 and 27-30 are pending.

Priority

Receipt is acknowledged of a certified copy of the priority document *in this National Stage application from the International Bureau* submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 11/207 and 7/3/08 were considered by the examiner.

Examiner's Notes

In claim 19, the lineout through "or 18." appears to include the period (which would be correct). However, the line is very close and it is difficult to be sure that the period is lined out. Therefore, the examiner requests that upon reply, applicants make sure that the period is not included in the middle of the claim and only appears at the end of the claim.

Claim 6 as written includes the phrase "chosen from the group including". Proper Markush language is "selected from the group consisting of". The examiner suggests rewording the claim to include the Markush language. **Note: MPEP 2111.03**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-23 and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-23 are currently written are vague and indefinite. Claim 21 recites the method according to claim 27 and claims 22-23 recite the method according to claim 28. However, claims 27 and 28 are directed to a solution. Therefore claims 21-23 have improper dependency. The examiner believes that this is a typo and claims 21-23 should actually be directed to a medical solution (the only other option would be for claim 21 to depend from claim 17 and claims 22-23 to depend from claim 18 however claims 17 and 18 lack the appropriate antecedent basis for the third and fourth solutions). Therefore, in the interest of furthering prosecution, claims 21-23 will be interpreted as medical solutions. This also affects claims 29-30 which depend from claims 21 and 23. It is noted that it is difficult to determine which is the correct interpretation for claims 21-23. The examiner has made the best estimate as to what the proper interpretation should be, however, if applicants disagree applicants should clearly indicate in their next response the correct dependence for claims 21-23.

Claims 29-30 are included in the rejection as they depend on a rejected base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 11-14, 16-17, 20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zander (US Patent No. 5296242, cited on PTO Form 1449) in view of Duponchelle et al. (US Patent No. 6309673).

Applicant Claims

The instant application claims a medical solution comprising a first single solution comprising bicarbonate and carbonate in such proportions that a partial pressure of carbon dioxide in the fist single solution is the same order of magnitude as a partial pressure of carbon dioxide in the atmosphere and a second single solution comprising an acid wherein said first and second single solutions are mixed after terminal sterilization to form a final solution wherein said second single solution has a pH of 1 to 1.5 and said final solution has a pH of 7.0 to 7.6.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Zander is directed to aqueous solutions and the use thereof. It is taught that bicarbonate-containing dialysis liquids are known. However these solutions are not stable because there is always a risk that carbon dioxide (CO_2) escapes from a bicarbonate solution and consequently the composition of the solution changes (column 1, lines 4-13). In the prior art discussion, Zander indicates prior art which discloses liquid in which in contact with atmospheric air do not change their overall CO_2 content and which contain certain concentrations of alkali carbonate and alkali bicarbonate. These liquids have a CO_2 partial pressure which corresponds to that of atmospheric air (column 1, lines 55-65). The invention of Zander was to obtain a sterilizable aqueous solution with physiological values of the pH, bicarbonate concentration and CO_2 partial pressure which can be stored in air without requiring special equipment for preventing a diffusing of or in of carbon dioxide (columns 1-2, lines 66-4). It is taught that if pH-value bicarbonate concentration and the CO_2 partial pressure corresponds to the

physiological blood plasma levels (pH of 7.4 ± 0.05 and partial pressure of 40 mm Hg) then on using such solutions there is no overdosing or underdosing relative to the acid-base status (column 2, lines 35-50). The invention utilizes two separately stored single solutions to be combined prior to use wherein one is bicarbonate-free acid solution and the other is a bicarbonate-containing alkaline solution (column 2, lines 5-10). The solutions are sterilizable (column 2 lines 30-31). The acid solution can additionally contain calcium and magnesium ions as well as glucose and/or amino acids (column 4, lines 32-35). The exemplified solutions were taught as stable and prevent a diffusing in or out of CO_2 (column 6, lines 42-46). As claimed the sterilizable solution is in the form of two separately stored single solutions which are combinable. One solution is bicarbonate-free acid solution the other is a bicarbonate containing solution comprising alkali bicarbonate and alkali carbonate (claim 1). It is taught that a pH of about 5 prevents denaturation or brown colouration of glucose or amino acids (column 2, lines 30-34).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Zander does not teach the instantly claimed pH values. Zander does not teach the addition of electrolytes to the bicarbonate solution (prior to mixing). Zander does not specify a multi-compartment bag. Zander does not specify the acid is HCl. However, these deficiencies are cured by Duponchelle et al.

Duponchelle et al. is directed to bicarbonate-based solution in two parts for dialysis or continuous renal replacement therapy. It is taught that bicarbonate solutions for injection and for certain types of dialysis need to be sterile. Sterile filtration, steam

sterilization, radiation or another suitable sterilization method may be used (column 3, lines 39-61). Multi-compartment containers can be utilized to store and sterilize the solutions (columns 3-4, lines 65-67 and 1-2 and figure 1). The solution utilized is a two-part bicarbonate containing solution. The alkaline bicarbonate solution has a pH adjusted to about 8.6 to 10. The second part is an acidic concentrate having a pH with a range of about 1 to 3. When mixed together the pH of the solution ranges from about 6.5 to 7.6 (column 4, lines 33-44). The pH of the alkaline bicarbonate is chemically adjusted upwards at the time of manufacture to more alkaline values. Chemically increasing the pH of the bicarbonate component upwards when combined with a dextrose component at a low pH yields a stable product that does not need a gas barrier (column 4, lines 45-57). When the bicarbonate posses this higher pH, the bicarbonate based concentrate is in a steady state and is in equilibrium with the ambient air (column 5, lines 5-10). The multi-chamber container is utilized to store and house the separate solutions (column 5, lines 18-30). The bicarbonate utilized is sodium bicarbonate (table 1). The acidic concentrate contains a physiologically tolerable acid to adjust the pH. Examples include hydrochloric acid, sulphuric acid, nitric acid etc. (column 7, lines 49-51). It is taught that the problem with utilizing organic acid is that the body has difficulty in metabolizing organic acids and in peritoneal dialysis the presence of organic acids and dextrose enhances the formation of glucose degradation products which in turn may damage the peritoneal membrane, that is why inorganic acids are preferred (column 3, lines 50-58). The pH of the acidic concentrate is chosen so that upon mixing of both the bicarbonate and acidic portions the resulting pH is in a

physiologic range (column 7, lines 34-45). The invention can also include an osmotic agent such as glucose or glucose polymers (column 8, lines 1-5 and table 3).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander and Duponchelle et al. and utilize a pH of the bicarbonate solution that is elevated towards a pH of about 10. One of ordinary skill in the art would have been motivated to utilize an elevated pH of the bicarbonate solution in order to form a solution that does not need a gas barrier. Both Zander and Duponchelle et al. teach that disadvantages out bicarbonate solutions is the escape of CO_2 from the solution. Zander teach utilizing a CO_2 partial pressure that is atmospheric so the solution can be stored in air without requiring special equipment for preventing a diffusing of or in of carbon dioxide, Duponchelle et al. teach utilizing an elevated pH so a gas barrier is not needed. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of Zander and Duponchelle et al. and overcome the known art problem of CO_2 concentration and utilize a partial pressure of CO_2 that is atmospheric and an elevated pH in order to produce a more stable bicarbonate solution that does not need the use of special equipment to keep the CO_2 concentration constant.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander and Duponchelle et al. and utilize an inorganic acid such as hydrochloric acid to adjust the pH of the acidic solution. One of ordinary skill in the art would have been motivated to utilize an inorganic acid like

hydrochloric acid as Duponchelle et al. that the problem with utilizing organic acid is that the body has difficulty in metabolizing organic acids and in peritoneal dialysis the presence of organic acids and dextrose enhances the formation of glucose degradation products which in turn may damage the peritoneal membrane. Therefore, one of ordinary skill in the art based on the teachings of Duponchelle et al. would have been motivated to utilize an inorganic such as hydrochloric acid in order to overcome the problems with organic acids.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander and Duponchelle et al. and utilize sodium bicarbonate as the source of bicarbonate in the dialysis solution. One of ordinary skill in the art would have been motivated to utilize sodium bicarbonate as Zander teach utilizing alkali bicarbonate and sodium bicarbonate which is exemplified by Duponchelle et al. is a particular type of alkali bicarbonate. It would have been obvious to one of ordinary skill in the art to try the specific alkali bicarbonate, sodium bicarbonate, as a person with ordinary skill has good reason to pursue known options within his or her technical grasp. **Note: MPEP 2141 [R-6]** *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007). It is noted that the use of alkali bicarbonates such as sodium bicarbonate results in electrolytes such as sodium being present in the bicarbonate solution.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander and Duponchelle et al. and utilize glucose in the solution. One of ordinary skill in the art would have been motivated to

utilize glucose as both Zander and Duponchelle et al. teach the addition of this component to the solution. Furthermore, Duponchelle et al. teach that glucose is an osmotic agent. Therefore, one of ordinary skill in the art would have been motivated to add glucose in order to maintain fluid balance (the purpose of an osmotic agent).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander and Duponchelle et al. and utilize a multi-compartment bag to store the solutions. One of ordinary skill in the art would have been motivated to utilize a multi-compartment bag as these are taught by Duponchelle et al. as typical devices utilizes to store these types of solutions. Furthermore, as evidenced by the figure of Duponchelle et al. these bags provide a convenient way to store the multiple solutions in one place which increases ease of use when sterilizing and using.

Regarding the claimed pH of the bicarbonate solution, Duponchelle et al. teach that elevating the pH results in a more stable final solution. The upper limit pH taught is about 10. While the exact pH is not disclosed by Duponchelle et al., it is generally noted that differences in degree of concentration do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Given that applicant did not point out the criticality of the bicarbonate pH of the invention and that Duponchelle et al. teach a pH that is substantially similar and Duponchelle et

al. and Zander teach a final solution pH which is the same as instantly claimed, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to determine where in a disclosed set of ranges is the optimum pH.

Regarding the claimed pH of the acidic solution, both Zander and Duponchelle et al. teach utilizing a final solution pH which is physiological (i.e. 6.5 to 7.6). Since the final pH is dependent on the pH of the bicarbonate and the pH of the acidic solution, it would have been obvious to one of ordinary skill in the art to adjust the pH of the acidic solution to a lower pH (such as a pH of 1-3) depending on the starting pH of the bicarbonate solution. Since the use of a higher pH for the bicarbonate is obvious (see above) and Duponchelle et al. teaches that the pH of the acidic concentrate is chosen so that upon mixing of both the bicarbonate and acidic portions the resulting pH is in a physiologic range. It would have been obvious to one of ordinary skill in the art to manipulate the pH of the acidic solution to ensure that the pH of the final solution is physiologic.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 8-10, 15, 18-19, 21-23, 25 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zander in view of Duponchelle et al. and in further view of Linden et al. (WO 0189478).

Applicant Claims

The instant application claims the solution further comprises a third single solution.

The instant application claims the solution further comprises a fourth single solution.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Zander and Duponchelle et al. are set froth above. Specifically, Zander teach the formation of dialysis solutions wherein the solution is broken into two different solutions wherein one solution is bicarbonate containing and the other is an acidic solution. Duponchelle et al. also teaches a two part dialysis solutions wherein one is bicarbonate containing and the other is acid containing. Both Zander and Duponchelle et al. teach that the two separate solutions are combined for use wherein the resulting pH of the final solution is at physiological pH. Both Zander and Duponchelle et al. teach that glucose can degrade.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Zander does not teach the addition of a third or fourth single solution. Zander does not specify that the sterilization is heat sterilization at a temperature of at least 100 °C. However, these deficiencies are cured by Linden et al.

Linden et al. is directed to medical solution in a multiple compartment container. Linden et al. teaches that scientists have become aware of the toxicity of decomposition compounds of carbohydrates in peritoneal dialyses. Since patient on peritoneal dialysis uses between 8 and 20 liters of dialysis solution every day, depending on the treatment this results in the consumption of 3-7 tons of solution with 1.5-4% glucose every year. If the glucose undergoes decomposition this also means a non-negligible amount of decomposition compounds are consumed. It is well know that some patient experience pain during inflow of dialysis fluid and this pain is believed to be results of glucose degradation (page 1, lines 16-31). The multiple compartment containers comprises at least two compartments, preferably three or more compartments. In at least on of the compartments there is a carbohydrate compound in solution with at least one sulphite compound in one of the compartments to reduce the formation or scavenge already produced decomposition products from the carbohydrate. Commonly used medical solutions either in single or multiple compartment containers contain glucose in the final solution in a concentration in the range of 1.5 to 4% preferably 1.5, 2.5 or 4% (column 6, lines 19-29). As exemplified, one compartment (compartment 44) comprises glucose in 30% and electrolytes at a pH of 3.2, another compartment (compartment 45) comprises glucose in 50% and electrolytes at a pH of 3.2 and a third compartment (compartment 9) comprises a bicarbonate and sodium. It is taught if one mixes compartment 44 and 9 you get a final glucose concentration of 1.5%, mixing compartment 45 and 9 gives a glucose concentration of 2.5%, mixing compartments 44, 45 and 9 gives a glucose concentration of 4% (example 1, pages 15-16). Sterilization of the solutions is

performed using conventional sterilization such as heat treatment with a temperature of 100 to 150 °C.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander, Duponchelle et al. and Linden et al. and utilize heat sterilization at a temperature of 100 to 150 °C. One of ordinary skill in the art would have been motivated to utilize heat sterilization at this temperature as Zander teaches the solutions as sterilizable and Duponchelle et al. teach that dialysis solutions must be sterilized before use and one method of sterilization is steam sterilization, therefore, the use of heat sterilization, which is a conventional form of sterilization would have been obvious to one of ordinary skill in the art base don the teachings of Duponchelle et al. and Linden et al.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander, Duponchelle et al. and Linden et al. and utilize two additional glucose solutions to form the medical solutions for dialysis. One of ordinary skill in the art would have been motivated to utilize two additional glucose solutions in order to manipulate the final glucose concentration as taught by Linden et al. The use of two different glucose solutions allows for the formation of final glucose concentrations of 1.5, 2.5 or 4% which are typical amounts of glucose used in dialysis solutions as taught by Linden et al.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander, Duponchelle et al. and Linden et

al. and utilize a multi-compartment bag for storage of the solutions. One of ordinary skill in the art would have been motivated to utilize a multi-compartment bag as both Duponchelle et al. and Linden et al. teach these are standard bag for housing and use of these types of medical solutions.

Regarding the claimed electrolytes, the exemplified glucose and bicarbonate solutions exemplified by Linden et al. all comprise electrolytes.

Regarding the claimed arrangement of the solutions, Zander, Duponchelle et al. and Linden et al. all teach keeping the solutions separate prior to use. Therefore, based on the teachings of the three references one of ordinary skill in the art would have been motivated to keep the solutions separate in a multi-compartment bag until use and then mixing the solutions to form the final solution.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 11-14, 16-17, 20 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-11, 14-17, 20 and 21 of copending Application No. 11658001 (USPGPUB No. 20080085325). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a medical solution comprising a first single solution comprising bicarbonate and carbonate in such proportions that a partial pressure of carbon dioxide in the first single solution is of the same order of magnitude as a partial pressure of carbon dioxide in the atmosphere and a second single solution comprising an acid wherein the first and second single solutions are mixed after terminal sterilization to form a final solution wherein said second single solution has a pH of 1.0 to 1.5 and the final solution has a pH of 7.0-7.6.

Copending '001 claims a medical solution wherein before use is divided into at least first and second single solutions wherein after terminal sterilization and upon use are mixed together to form a ready-for-use solution having a pH of 6.5-7.6. The second single solution as claimed has a pH below 2.5 and comprises HCl. The first solution as claimed comprises bicarbonate and carbonate in such proportions that he partial pressure of carbon dioxide is on the same order of magnitude as the partial pressure of carbon dioxide in the atmosphere. The claimed pH of the first solution is 10.1-10.5. The solution as claimed comprises glucose in the second single solution. The solution as claimed comprises electrolytes. Also claimed is a method for producing a medical solution comprising providing said at least first and second single solution in separate compartments and terminally sterilizing said solutions. Multi-compartment bags comprising the solution are also claimed.

Therefore both the instant application and copending '001 claim the same solutions with the same ingredients, the same pH and the same partial pressure of carbon dioxide. Since copending '001 claims a multi-compartment bag, it would have

been obvious to one of ordinary skill in the art to store the separate solutions in the multi-compartment bag and then after sterilization mix the solutions as sterilization and mixing are claimed by copending '001.

It is noted that applicants open claim language of comprising does not exclude the presence of other buffers such as phosphate.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Abigail Fisher/

Examiner, Art Unit 1616